

Clinical Policy: Axitinib (Inlyta)

Reference Number: PA.CP.PHAR.100

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for axitinib (Inlyta[®]).

FDA Approved Indication(s)

Inlyta is indicated for treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

Policy/Criteria

It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Inlyta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Renal Cell Carcinoma (must meet all):

1. Diagnosis of RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. One of the following (a or b):
 - a. For RCC with predominant clear cell histology: Member has received one prior therapy (e.g., Votrient; Sutent);
 - b. RCC with non-clear cell histology (off-label);
5. Dose does not exceed 10 mg orally twice daily.

Approval duration: 6 months

B. Thyroid Carcinoma – Off-label Use (must meet all):

1. Diagnosis of follicular, Hurthle cell or papillary thyroid carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Disease is iodine-refractory and either unresectable or metastatic;
5. Request meets one of the following (a or b):
 - a. Dose does not exceed 10 mg orally twice daily;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Renal Cell and Thyroid Carcinomas (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy (e.g.: no disease progression; not experiencing unacceptable toxicity).
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 10 mg twice daily;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Axitinib is an oral agent that works by inhibiting receptor tyrosine kinases, including vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3. These receptors are implicated in pathologic angiogenesis, tumor growth, and cancer progression.

FDA Approved Indications:

Inlyta is a kinase inhibitor/oral tablet formulation indicated for:

- Treatment of advanced renal cell carcinoma after failure of one prior systemic therapy

Appendices

Appendix A: Abbreviation Key

VEGFR: vascular endothelial growth factor receptor

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Age, specialist and dosing added. Renal cell carcinoma: definition of “advanced” removed given the additional requirement of a prior systemic therapy. References reviewed updated.	02/18	

References

1. Inlyta Prescribing Information. New York, NY: Pfizer Labs, Inc.; August 2014. Available at <http://labeling.pfizer.com/ShowLabeling.aspx?id=759>. Accessed November 2017.
2. Axitinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed November 2017.
3. Kidney cancer (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed November 2017.
4. Thyroid carcinomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed November 2017.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.